

REMARKS

Applicant thanks the Examiner for the very thorough consideration given the present application.

Claims 1-87 are now present in this application. Claims 1, 24, 31, 47, 60, 77 and 85 are independent.

Reconsideration of this application is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1, 6-19, 22, 31-42, 45, 54, 60 and 65-75 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 3,019,790 to Militana in view of Redmon. This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

Because the rejection is based on 35 U.S.C. §103, what is in issue in such a rejection is "the invention as a whole," not just a few features of the claimed invention. Under 35 U.S.C. §103, "[a] patent may not be obtained . . ." if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The determination under §103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. See In re

O'Farrell, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety. See Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983).

In rejecting claims under 35 U.S.C. §103, it is incumbent on the Examiner to establish a factual basis to support the legal conclusion of obviousness. See, In re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. Uniroyal Inc. v. F-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), cert. denied, 488 U.S. 825 (1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986); ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie* case of obviousness. Note, In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The mere fact that the

prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. In re Eritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested or taught by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability of that claim against the prior art. In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

A showing of a suggestion, teaching, or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." C.R. Bard, Inc. v. M3 Sys. Inc., 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." See In re Dembiczak, 175 F.3d 994 at 1000, 50 USPQ2d 1614 at 1617 (Fed. Cir. 1999).

Militana clearly discloses a scissors type clamp such as a hemostat with a holder for an IV needle mounted thereon. Militana's scissors type clamp is made of two, relatively straight, elongated handle members 10 and 11. One end of each elongated handle members 10, 11 have a finger receiving member and the opposite end of each elongated handle member are opposed facing jaws 15, 16. The two, relatively straight, elongated handle members 10, 11 are pivoted

together about their jaws by a pivot pin 17. As a result, when Militana's finger receiving members 13 and 14 are separated, the jaws 15 and 16 are separated. In other words, to close the jaws, one closes the finger receiving members, and to separate the jaws, one separates the finger receiving members. In normal operation, as disclosed starting in col. 2, line 42, an operator places the jaws 15 and 16 astride a vein or artery with the end of the needle in close proximity of the artery. Force is applied by the operator's fingers on the finger pieces 13 and 14 to cause the handle members 11 and 12 to pivot about pivot pin 17 toward each other, causing jaws 15 and 16 to come toward a closed position so that the walls of the artery are engaged and squeezed together.

Claims 1, 31, 47 and 60 recite a combination of features including the forcep arms being cranked adjacent the pivot joint whereby the handles are splayed apart with the blades in engagement. Militana's device is clearly not capable of operating in this manner because of its construction and arrangement of parts.

The Office Action admits that Militana fails to disclose this feature by stating that "Militana fails to form the forcep arm so that the handles are splayed apart when the blades are in the engaged position and spring urged apart."

In an attempt to provide this feature, the Office Action turns to Redmon. Redmon discloses a significantly different type of device than does Militana. Redmon is directed to a surgical instrument having two legs that are not straight. In fact, the legs of the Redmon device are significantly bent with

respect to two approximately mutually perpendicular axes. Each leg is connected by a pivoting means 20 where it bends outwardly away from the other leg. Each leg has blade portion, 17 or 18, at one end that is bent at an approximately right angle to a longitudinal axis of the elongated portion of the leg that is designed to be grasped by an operator's fingers.

In normal operation, as disclosed starting in col. 5, line 25, Redmon inserts its surgical instrument into an incision made in a body in a closed position, rotates it about ninety degrees to increase the vertical height of the incision, squeezes the elongated handle portions 13, 14 toward each other which causes the generally perpendicular blade positions 17, 18 to move away from each other during pivoting about pivot pin 20 to permit a fiber optic probe to provide an image of a ligament that is subsequently cut. After the ligament is cut, the handle portions 13, 14 are released so that a spring can bias the blade portions from an open to a closed position to facilitate removal of the instrument from the incision.

Despite the significant structural differences between Militana's vein-clamping hemostat and Redmon's carpal tunnel syndrome expander, the Office Action concludes that it would have been obvious to form the handles of Militana to be spring urged to a splayed position "as Redmon teaches that this forms a forceps device with normally closed blades."

Applicant respectfully disagrees for a number of reasons.

Firstly, Militana and Redmon have fundamentally different structures and operate in fundamentally different ways, so that providing Redmon's bias springs in Militana would achieve the opposite result in Militana as it achieves in Redmon. That is, whereas Redmon's bias springs bias the blades of its instrument closed, if such springs were added to Militana, Militana's jaws/blades would be biased open, i.e., just the opposite of how Redmon's blades are biased.

The Office Action does not explain why one of ordinary skill in the art would have any incentive to provide springs in Militana when Militana has no need for them, when they would make Militana's device more complicated and expensive than it is in its present workable form, and when they would bias Militana's blades open when Militana does not need to have them biased open in normal operation.

Secondly, the Office Action never addresses the fact that providing Redmon's springs in Militana would bias Militana's instrument's blades open, which would reduce the ability of a user to insert Militana's instrument into an incision. This actually teaches away from modifying Militana as suggested.

Thirdly, Militana and Redmon solve substantially different problems in substantially different ways. As noted above, Militana seeks to grasp a vein so that a hypodermic needle carried by the instrument can be inserted into the vein, whereas Redmon seeks to grasp nothing and, instead, seeks to spread flesh away from a ligament to be severed by another instrument. These fundamental

differences between the references also teach away from combining these references, as suggested.

A fair, balanced appraisal of these two references reveals that they (1) have substantially different physical structures; (2) open and close in substantially opposite ways; (3) are normally used for substantially different operations; and (4) in normal operation, perform significantly different functions.

In view of this, Applicant respectfully submits that one of ordinary skill in the art would have no motivation to combine these two references, as suggested.

Moreover, even if Militana were modified as suggested, Militana's handles would not be splayed apart with the blades in engagement, as recited, for reasons explained above.

Furthermore, claims 1, 31, 47 and 60 positively recite a combination of features, including a tube gripping means for releasable securing the exterior of a length of tubing. Militana does not disclose this feature. Militana has no gripping means to secure the exterior of a length of tubing. Rather, the inside of Militana's tubing 35 grasps the hypodermic needle's base member 34, as shown in Fig. 5, for example. The Office Action incorrectly states that element 31 is a tube gripping means. Actually, element 31 is disclosed as a bracket that retains the hypodermic needle's base member 34, not as something that retains the tubing 35.

Accordingly, even if it were proper to modify Militana in view or Redmon (which it is not for reasons discussed herein), the resulting reference combination would not meet, or render obvious, the claimed invention.

Further, with respect to claims 22, 45 and 58, Militana's toggle arms are not disclosed as having any spring effect and their function is disclosed as moving the hypodermic needle as the handles 10 and 11 are manually closed by a user. The Office provides no proper motivation for one of ordinary skill in the art to replace these toggle arms with bias springs. In fact, if they were replaced with bias springs, a user would not appear to have proper control to move the hypodermic needle forward and backward as the spring bias would tend to withdraw the needle constantly.

With respect to claims 17, 18, 40, 41 and 54, the burden is on the Office to provide objective factual evidence that the claimed blade shape is obvious and the Office completely fails to provide any such evidence. A factual inquiry whether to modify a reference must be based on objective evidence of record, not merely conclusory statements of the Examiner. See, In re Lee, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002). This underscores the failure of the Office Action to comply with existing case law requirements for supporting a rejection under 35 U.S.C. §103.

Moreover, whether something is within the skill of one of ordinary skill in the art to accomplish, as alleged, begs the question of whether or not a skilled

worker would be motivated to do so – an issue which is simply not addressed by this rejection, thereby making the rejection fundamentally improper.

Accordingly, this rejection is improper and should be withdrawn.

With regard to dependent claims 6-19, 22, 32-42, 45, 54, 61, 62, 63, 64 and 65-75, Applicant submits that these claims depend, either directly or indirectly, from one of independent claims 1, 24, 31, 47 and 60 which are allowable for the reasons set forth above, and therefore each of dependent claims 6-19, 22, 32-42, 45, 54, 61, 62, 63, 64 and 65-75 is allowable based on their dependence from one of claims 1, 24, 31, 47 and 60. Reconsideration and allowance thereof are respectfully requested.

Claims 2-5, 21, 24-30, 44, 47, 53, 55, 57, 58 and 61-64 stand rejected under 35 U.S.C. §103(a) as unpatentable over Militana in view of Redmon and further in view of U.S. Patent 4,608,982 to Pollard. This rejection is respectfully traversed.

This rejection is improper to the extent that it is based on the Militana-Redmon reference combination for reasons stated above, and because Pollard is not applied to remedy the deficiencies in the Militana-Redmon reference combination.

The Office Action admits that neither Militana nor Redmon's blades are arcuate in shape with open mouths facing each other. In an attempt to remedy

this deficiency, the Office Action turns to Pollard, which discloses forceps with gripping jaws having an arcuate shape to that when closed, they form a retaining passage for a catheter 23.

The Office Action concludes that it would be obvious to make Militana's device to have an arcuate, open mouth configuration as taught by Pollard "as this shape would help in the delivery of blade (22) and tube (35)."

Applicant respectfully disagrees.

Firstly, Militana's hypodermic needle 22, is delivered into a vein by moving toggles 26 and 27 and the hypodermic needle is held to the hemostat by a bracket and not by blades 15 and 16. Militana's blades 15 and 16 do not hold a tube or a needle, and are only used to hold a vein. Thus, there is no need to modify Militana's jaws/blades 15 and 16 to hold a tube or needle because Militana already provides a separate bracket to do this.

Secondly, to provide Militana's jaws/blades 15 and 16 with facing arcuate shapes would be counterproductive to the operation of Militana in the sense that if Militana's blades 15 and 16 had such a facing arcuate shape, they would not be able to effectively squeeze the vein. Instead, they would envelop the vein and not be able to as effectively squeeze and hold the vein in position as can be done with Militana's substantially parallel jaw faces to permit insertion of the hypodermic needle. Accordingly, Militana teaches away from being modified as proposed by the Office Action.

Accordingly, the Office Action fails to make out a *prima facie* case of proper motivation to modify Militana as suggested and fails to make out a *prima facie* case of obviousness of the claimed invention.

Allowed and Allowable Subject Matter

Applicant acknowledges with appreciation the allowance of claims 77-87, and the indication of allowable subject matter in claims 20, 23, 43, 46, 56 and 59. Applicant has not re-written claims 20, 23, 43, 46 and 56 in independent form, however, because of Applicant's belief that the claim(s) on which each of dependent claims 20, 23, 43, 46 and 56 depend(s) is allowable, for reasons stated above.

Additional Cited References

Because the remaining references cited by the Examiner have not been utilized to reject the claims, but have merely been cited to show the state of the art, no comment need be made with respect thereto.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the

outstanding Office Action, and as such, the present application is in condition for allowance.

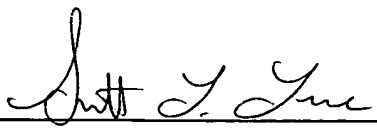
If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone Robert J. Webster, Registration No. 46,472, at (703) 205-8034, in the Washington, D.C. area.

Prompt and favorable consideration of this Amendment is respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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